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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,340	02/16/2001	Ming-Hui Wei	CL000763	1842
25748	7590	12/29/2004	EXAMINER	
CELERA GENOMICS CORP. ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY 45 WEST GUDE DRIVE C2-4#20 ROCKVILLE, MD 20850			RAMIREZ, DELIA M	
			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 12/29/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,340

Applicant(s)

WEI ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,8,9 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-26 is/are allowed.
- 6) ☒ Claim(s) 4,8,9,24 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: seq listing 60/197590.

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DETAILED ACTION

Status of the Application

Claims 4, 8-9, 24-30 are pending.

Applicant's remarks submitted in a communication filed on 10/4/2004 are acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 4, 8-9, 24-30 were rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility.

3. Claims 4, 8-9, 24-30 were also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

4. These rejections have been discussed at length in an Office Action mailed on 6/3/2004.

5. Applicants argue that the polypeptide of SEQ ID NO: 2 shows homology to the specific subfamily 2 within the UDP-glucuronosyltransferase family as evidenced by the homologous polynucleotides listed in Figure 1. Furthermore, Applicants argue that UDP-glucuronosyltransferases have specific functions and utilities asserted in the specification and known in the art. Applicants submit that (1) Jin et al. teaches the substrates that class 1 and class 2 family members of the UDP-glucuronosyltransferase family, and (2) the UDP-glucuronosyltransferase family of enzymes are known to metabolize the substances listed in the specification. Thus, one of skill in the art would recognize that the claimed invention does have utility. It is Applicant's contention that the polypeptide of the present

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invention has high homology to UDP-glucuronosyltransferases, and that the specification has been specific in regard to the biological function of the polypeptide of SEQ ID NO: 2.

6. Applicant's arguments have been fully considered. In view of (a) the fact that the polypeptide of SEQ ID NO: 2 appears to have at least 60% sequence identity to UDP-glucuronosyltransferases of the prior art, (b) the structural homology of the polypeptide of SEQ ID NO: 2 to class 2 UDP-glucuronosyltransferases, and (3) the art as well as the specification teach known UDP-glucuronosyltransferase substrates, which would be expected to be targeted by the polypeptide of SEQ ID NO: 2, these rejections are hereby withdrawn.

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 4, 8-9, 24, 27-30 remain rejected under 35 U.S.C. 102(e) as being anticipated by Policky et al. (U.S. Publication No. 2004/0029125; corresponding 371 U.S. application is 10/258080) and Policky et al. (WO/ 01/79468 A2, PCT/US01/11869). This rejection has been discussed at length in an Office Action mailed on 6/3/2004.

9. Applicants argue that the Examiner did not provide a copy of the provisional application to which the non-provisional US application and PCT application of Policky et al. claim priority (U.S. provisional application No. 60/197590). Furthermore, Applicants argue that the Examiner only provided an alignment which is a polynucleotide to amino acid sequence alignment and not one between two polynucleotide sequences. According to Applicants, this is not supporting evidence and thus the applications of Policky et al. are not available as prior art. Furthermore, since no polynucleotide to polynucleotide sequence alignment was provided, there is no factual evidence to show that the

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polynucleotides of Policky et al. are completely complementary to SEQ ID NO: 1 as required in claim 30 or consist of SEQ ID NO: 1, as required by claim 4(b).

10. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. The alignment provided by the Examiner uses the polynucleotide of Policky et al. as disclosed in the US application in view of the fact that the Examiner is relying on this application and the PCT application. As stated in the Office Action, the specification of the non-provisional US application and that of the PCT are identical. U.S. provisional application No. 60/197590 is relied upon solely to establish when the polynucleotide sequence of the non-provisional and PCT applications was first disclosed. The Examiner regrets that due to a clerical error a copy of the provisional application was not mailed with the previous Office Action. However, as clearly stated in the Conclusion section of the previous Office Action (section 11), Applicants can always contact the Examiner regarding questions related to the examination of the instant application. Please note that the previous Office Action clearly states that if the Examiner cannot be reached, her supervisor can be contacted. A copy of U.S. provisional application No. 60/197590 can be accessed via the public PAIR website at <http://portal.uspto.gov/external/portal/pair>. A courtesy copy of the relevant pages of that application are being submitted herein (sequence listing). The polypeptide of SEQ ID NO: 1 in that provisional application is encoded by the polynucleotide of SEQ ID NO: 2. Unless shown otherwise, the polynucleotide of SEQ ID NO: 2 in that provisional application is that disclosed in the non-provisional and PCT applications of Policky et al.

The Examiner also submitted a polynucleotide to amino acid sequence alignment, because the instant claims are directed to polynucleotides encoding the polypeptide of SEQ ID NO: 2, host cells, vectors, and a process to recombinantly produce the polypeptide of SEQ ID NO: 2. A polynucleotide to amino acid sequence alignment is proper evidence to show whether a polynucleotide encodes the recited polypeptide. Therefore, as shown by the alignment provided, claims which encompass polynucleotides

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that encode the polypeptide of SEQ ID NO: 2 are clearly anticipated by the polynucleotide of Policky et al. It is also noted that nowhere in the previous Office Action did the Examiner indicate that the polynucleotide of Policky et al. is completely complementary to the polynucleotide of SEQ ID NO: 1, or that it consists of the polynucleotide of SEQ ID NO: 1. Applicants are reminded that claims 4 and 30 are also directed to (1) an isolated nucleic acid encoding the protein of SEQ ID NO: 2, and (2) a nucleic acid molecule consisting of a nucleotide sequence that is completely complementary to the nucleotide sequence of an isolated nucleic acid encoding the protein of SEQ ID NO: 2, respectively, which is clearly taught by Policky et al. Therefore, claims 4, 8-9, 24, 27-30 are clearly anticipated by the teachings of Policky et al.

Art of Interest

11. The Examiner indicated in the previous Office Action that U.S. Publication No. 20040029221 (Baker et al.) discloses a polypeptide 100% identical to the polypeptide of SEQ ID NO: 2 as well as the corresponding polynucleotide. The corresponding non-provisional application claims priority to provisional application No. 60/209832. The Examiner stated that priority could not be verified at the time the previous Office Action was mailed and if it was later verified that SEQ ID NO: 521-522 of U.S. Publication No. 20040029221 were first disclosed in provisional application No. 60/209832, the teachings of Baker et al. would not be considered as new ground(s) of rejection.

12. It is noted that at this time, the priority claim to provisional application No. 60/209832 has not been verified.

13. Applicants argue that if no rejection was made, a subsequent Office Action cannot be made final. Applicants also argue that even if the Office properly rejected any claims based on the teachings of Baker et al., the Examiner did not provide factual evidence to support such rejection since only a polynucleotide to amino acid sequence alignment was provided based on the sequence disclosed in U.S.

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Publication No. 20040029221. Thus, the evidence provided refers to a later filed application which cannot be used as prior art. Furthermore, according to Applicants, the Examiner did not provide a nucleotide to nucleotide sequence alignment of the polynucleotide of Baker et al. and SEQ ID NO: 1 of the instant application. Thus, there is no factual evidence that the polynucleotide of Baker et al. is completely complementary to SEQ ID NO: 1, or consists of SEQ ID NO: 1, as required by claims 30 and 4(b), respectively.

14. Applicant's arguments have been fully considered. In view of the fact that no rejection has been made, and the priority claim of U.S. Publication No. 20040029221 cannot be determined at this time, this Office Action has not been made final. While no rejection is being made at this time, even if priority has been determined, an alignment of the polynucleotide of Baker et al. as disclosed in the US non-provisional application would be considered proper evidence in view of the fact that the Examiner would be relying on the non-provisional application and use the provisional application solely to establish a priority date. In regard to arguments that the alignments provided would not support a rejection based on the teachings of Baker et al., it is noted that the Examiner has not stated that the polynucleotide of Baker et al. would anticipate a claim directed to a polynucleotide completely complementary to SEQ ID NO: 1 or a polynucleotide which consists of SEQ ID NO: 1. Applicants are reminded that claim 4 is also directed to an isolated polynucleotide encoding the polypeptide of SEQ ID NO: 2, and claim 30 is also directed to a polynucleotide consisting of a nucleotide sequence which is completely complementary to a nucleotide sequence that encodes the polypeptide of SEQ ID NO: 4. Thus, if the priority claim is verified, the polynucleotide of Baker et al. would anticipate claims directed to polynucleotides encoding the polypeptide of SEQ ID NO: 2, and complete complements thereof.

Allowable Subject Matter

15. Claims 25-26 appear to be allowable over the prior art of record.

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Conclusion

16. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.


17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
November 9, 2004


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800-
1600